Appln No.: 09/944,326
Amendment Dated: April 29, 2005
Reply to Office Action of October 29, 2004

REMARKS/ARGUMENTS

This is in response to the Office Action mailed October 29, 2004 for the above-captioned application. Reconsideration and further examination are respectfully requested

In response to the Examiner's remark, the claims are presented again to list claims 4, 5, 17, 18 and 21 as withdrawn.

An Information Disclosure Statement was mailed in this Application on April 12, 2004, and was plainly received by the USPTO since the credit card authorization that accompanied the submission was processed in the same month. However, no record in the PAIR exists, and therefore it appears that the Patent Office mail room mishandled the IDS. Applicants now enclose a further copy of the form PTO 1449, and request that the finality of the rejection be withdrawn for consideration of the Information Disclosure Statement consistent with the collection of payment for filing after the first Official Action. Copies of the references are available in the parent case, Serial No. 09/913,325 but will be provided upon request.

Withdrawal of the finality of the rejection in this case is also appropriate in view of the fact that the Examiner maintained the provisional rejection of claims 1-3, 6-9, 12-16 and 22-27 for obviousness-type double patenting in view of co-pending application serial no. 10/080,794. The Examiner asserts that the two-way test need not be applied because this is only applicable where a patent issues first on the later filed application. However, if this application issues first, there is no basis for the double-patenting rejection, and if the '794 application issues first (which it presumably will since the issue fee has been paid) make the distinction between applications and patents illogical.

It is further noted that once the '794 application issues, that any provisional rejection now pending that fails to take into account the fact that the '794 patent will issue first will be moot, and that a reopening of prosecution would be required. At that time, the Examiner will need to take into account the fact that the pace of the two application has been controlled by the patent office, not applicants (the '794 application was allowed without an official action) and that the specific species claimed in the '794 application is not disclosed and therefore could not have been claimed in this application. Applicants therefore suggest that this rejection should be withdrawn, which would place claims 3, 12-16, 24 and 25 in allowable form, and require withdrawal of the restriction with respect to claims 17 and 18.

On the merits, the Examiner has maintained the anticipation rejection of claims 1, 2, 6, 7, 8, 22, 23 and 27 based on Sensibar, and has refused to accept Applicants argument that Lipofectin, the lipid carrier used *in vivo* in Sensibar is not suitable for human pharmaceutical use. The Examiner cites US patent No. 5,998,148, but this does not contradict the statement that

Lipofectin is unsuitable for human treatment. This merely makes a general statement that the materials that enhance uptake of oligonucleotides may be added to pharmaceutical and other **compositions** and includes Lipofectin in a list of examples. The examiner also refers to US Patent No. 5,855,911, one of the two patents cited in the application as disclosing suitable carriers for use in this application, as evidence that Lipofectin is suitable for human use. In the '911 patent, however, the only mention of Lipofectin is in the background, and nothing in this statement says that Lipofectin is suitable for use in a human therapeutic. Thus, this reference also does not refute Applicants argument.

Finally, Applicants note the Examiner's comments that "the claims as amended do not limit the use of the compositions to humans, the intended recipients are mammals." Applicants agree with this statement, but do not understand its significance to the issue presented. The claims in this application are composition claims. The claim requires, however, two features: (1) that the pharmaceutical carrier be such that the composition is pharmaceutically acceptable for use in a human patient; and (2) that the composition reduce expression of TRPM-2 in a mammalian (not necessarily human) subject. Nothing about these limitations detracts from the significance of the fact that Lipofectin is unsuitable as a pharmaceutical carrier for administration to humans.

For the foregoing reasons, Applicants submit that all of the pending claims are in form for allowance. Withdrawal of the finality of the rejection and allowance of all claims are respectfully urged.

In the event that the Examiner refuses to withdraw the finality of the rejection, Applicants enclose a Notice of Appeal for this file together with the fee.

Respectfully Submitted,

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